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DEC 27 2000

Asclepion

Asclepion-Meditec AG Pruessingstrasse 41, 07745 Jena, Germany

510(k) SUMMARY

MEGATRON III/VI

This 510(k) summary of safety and effectiveness for the Asclepion-Meditec AG MEGATRON is submitted in accordance with the requirements of 21 CFR Part 807 Subpart E § 807.92 and follows the DSMA Office of Health and Industry Programs Guidance: Premarket Notification 510(k) – Regulatory Requirements for Medical Devices (HHS Publication FDA 95-4158, August 1995) concerning the requirements for a 510(k) Summary and Statement.

Applicant:	Asclepion-Meditec AG
Address:	Pruessingstrasse 41 07745 Jena, Germany
Contact Person:	Dr. Dirk Colditz Vice President Operations
Phone: **Fax:** **e-mail:**	+49 3641 65 3453 +49 3641 65 3448 ctz@asclepion.com
Preparation date:	June 20th, 2000
Device name:	Phacofragmentation system MEGATRON III and VI
Common Name:	MEGATRON III / MEGATRON VI
Classification Name:	Ophthalmic Devices – Phacofragmentation system (21 CFR 886.4670) Poduct code: HQC – Unit, Phacofragmentation Panel: OP
Legally marketed devices (SE):	Alcon Laboratories, Alcon Series 20000 Legacy Phacoemulsifier (K952213), Allergan, Inc.,AMO Diplomax/Opsys Console (K971186) Mentor O&O, Inc., Mentor Odyssey Phacoemulsification System. (K912904) Paradigm Medical Industries, Precisionist Thirty Thousand (K953447)
Device Description:	The Geuder Megatron III performes the phacoemulsification by using ultrasonic power. A handpiece for phacoemulsification is connected by a cable to the device. The construction and the design of the handpiece are nearly the same as in the case of the handpieces of the predicated devices. Irrigation and aspiration are lead in silicone tubes from the Geuder Megatron to the handpiece, where the tubes are connected to the irrigation and aspiration channel. MEGATRON VI performs irrigation/aspiration only. The surgeon is able to control the ultrasonic power, irrigation and aspiration by a special footswitch, which is provided by Geuder. The peristaltic pump offers a Venturi-effect. Handpiece and tubing system are sterilizeable by autoclaving.

Intended Use:

MEGATRON III is a ophthalmic surgical system for irrigation/aspiration and phacoemulsification. MEGATRON VI is intended for irrigation/aspiration only.

The MEGATRON is restricted to sale or use by licensed professionals in the United States.

Comparison to:

All features provided by the Megatron are comparable to the features of the predicated devices. In this way, the Megatron offers a frequency range from 30 to 55 Hz, the predicated devices provide 40 Hz.
The maximum vacuum of the Megatron reaches 550 mmHg, all compared devices offer 500 mmHg.
The maximum aspiration power of the Megatron is 50 ml/ min, the predicated devices provide 60, 44 and 22 ml/ min.
The comparison of the Megatron and the predicated devices showed, that there are no serious differences. The offered values of frequency, vacuum and aspiration power as the most important items of the devices are nearly the same.

Performance data:

None. The specifications and intended uses of the MEGATRON are the same or very similar to those of claimed predicate devices.
Because of this , performance data were not required.

CONCLUSION:

The Megatron provides nearly the same features, value ranges and items like the predicate devices do.
All devices work in the same technical way, all devices are using the same physical methods and basics.
The Megatron III/VI device is substantially equivalent to legally marketed devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 27 2000

Asclepion-Meditec AG
c/o Mr. William Kelly
Asclepion-Meditec, Inc.
2525 McGaw Avenue
Irvine, CA 92623-9791

Re: K002031
Trade Name: Phacoemulsification System MEGATRON III and VI
Regulatory Class: II
Product Code: 86 HQC
Dated: December 15, 2000
Received: December 18, 2000

Dear Mr. Kelly:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-6413. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

A. Ralph Rosenthal

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K 002031

Device Name: Megatron III/VI

Indications For Use:

MEGATRON III is a ophthalmic surgical system for irrigation/aspiration and phacoemulsification.
MEGATRON VI is intended for irrigation/aspiration only.
The MEGATRON is restricted to sale or use by licensed professionals in the United States.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Joel P. Glover

(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K002031

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR 801.109)